

## REMARKS

Applicant respectfully requests reconsideration of this application in view of the foregoing amendments and following remarks.

### **I. Status of the Claims**

Claims 26-28 and 40-42 are canceled without prejudice or disclaimer. Claim 31 is amended to be in independent form, claim 39 is amended to recite the components previously recited in claim 42, and claims 43-48 are amended to depend from claim 39. These amendments are made without prejudice or disclaimer, and Applicant reserves the right to pursue any canceled subject matter in one or more applications with the same rights of priority as the instant application.

Upon entry of these amendments, claims 31-36, and 38-39 and 43-48 will be pending. These claims are presented for reconsideration.

### **II. Office Interview**

Applicant thanks Examiners Claytor and Padmanabhan for the courtesies extended during the Office Interview on November 14, 2007. Applicant's summary of the substance of the interview is provided here.

During the interview, differences between the cited references and claimed invention were discussed. The Examiners indicated that the response submitted September 11, 2007, probably would overcome the prior art rejections, at least with respect to compositions comprising about 0.5% to 1% by weight isopropyl myristate, and Applicant agreed to consider amending the claims. The Examiners also indicated that an obviousness-type double patenting rejection might be made over co-pending application 10/734,640, and Applicant agreed to consider submitting a terminal disclaimer.

### **III. § 103 Rejections**

Applicant notes with appreciation the indication during the interview that the response submitted September 11, 2007, probably would overcome the prior art rejections, at least with respect to compositions comprising about 0.5% to 1% by weight isopropyl myristate ("IPM").

Applicant respectfully urges that the September 11 response supports the patentability of the full scope of the instant claims.

The Examiners indicated that they focused on compositions comprising about 0.5% to 1% IPM because the Rule 132 Declaration submitted with the September 11, 2007 response included data on compositions comprising amounts of IPM within that range (0.5%, 0.7%, and 0.9% in Section II and 1.0% in Section III), but not with amounts of IPM at the upper end of the recited range, e.g., up to 2% IPM. The Examiners also questioned whether data in the Rule 132 Declaration showed a declining affect of IPM at higher concentrations.

As noted at page 11 of the September 11 response, the compositions that are the subject of Section II of the Rule 132 Declaration (e.g., compositions comprising 0.5%, 0.7% and 0.9% IPM) demonstrate that IPM is an effective penetration enhancer at concentrations that are lower than those mentioned by Parab. Thus, these data demonstrate efficacy at the lower end of the recited range, but in no way imply a lack of efficacy at the upper end.

As explained in the interview, the apparent decline in penetration enhancement from 0.7% IPM to 0.9% IPM in the data depicted at page 5 of the Rule 132 Declaration is not statistically significant. This is evident when the reported data is read with the respective error bars. Indeed, the p value for the comparison of penetration enhancement at 0.7% IPM versus 0.9% IPM is 0.86, which is far above the 0.05 threshold for statistical significance. As explained in the September 11 response, the data show that IPM leads to statistically significant enhancement as compared to compositions without IPM at each amount of IPM tested, with a p value of 0.04 for the comparison of penetration enhancement at 0.9% IPM versus 0% IPM. There is no indication in the reported data that compositions comprising, for example, up to 2% IPM would not also demonstrate penetration enhancement.

Thus, when the September 11 response and Rule 132 Declaration are read as a whole, it is apparent that they support the patentability of the full scope of the pending claims.

#### **IV. Terminal Disclaimer**

During the interview, the possibility of a provisional obviousness-type double patenting rejection over co-pending application 10/734,640 was mentioned. Applicant respectfully traverses any such rejection.

As explained in MPEP § 804, obviousness-type double patenting arises only when a claim in the application at issue defines an invention that is merely an obvious variation of an invention claimed in the cited application or patent. That is not the case here. The claims of the '640 application are directed to methods of treating mastalgia using 4-OHT. While the claims might broadly encompass methods using the compositions recited here, they do not expressly recite such compositions. The Federal Circuit has explained that "'domination' . . . by itself, does not give rise to double patenting." *In re Kaplan*, 789 F.2d 1574, 1577 (Fed. Cir. 1986). *See also* MPEP § 804 (citing *Kaplan*).

Obviousness-type double patenting requires "obviousness," which has recently been explained by the Supreme Court in *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007). There, the Supreme Court held that the proper question for evaluating obviousness is "whether there was an apparent reason to combine the known elements in the fashion claimed." *KSR*, 127 S.Ct. at 1741. Where, as here, the claims of the '640 patent provide no reason to select the components of the compositions recited in the instant claims, there is no obviousness, and an obviousness-type double patenting rejection would be improper.

Moreover, in the context of a provisional obviousness-type double patenting rejection, the rejection should be withdrawn in the first filed application if it is the only issue remaining. Here, where the instant application was filed on the same day as the '640 application, and no other issue remains, a provisional obviousness-type double patenting rejection would be improper.

### CONCLUSION

Applicant believes that this application is condition for allowance, and an early indication to that effect is respectfully requested.

If there are any questions regarding this submission, or if any issue remains, the Examiner is invited to contact the undersigned directly in order to advance prosecution.

The Commissioner is authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of concurrently submitted papers, then Applicant petitions for such extension, under 37 CFR §1.136, and authorizes payment of the relevant fee(s) from the deposit account.

Respectfully submitted,

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